

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

CARMAELS & RANSFORD
Attn. Brunner, John M. O.
43-45 Bloomsbury Square
London WC1A 2BA
GRANDE BRETAGNE



NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

06/10/2009

Applicant's or agent's file reference

P050905WO

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/GB2009/001453

International filing date
(day/month/year)

10/06/2009

Applicant

CILAG GMBH INTERNATIONAL

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **16 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/B/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Elisabetta Sulis

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1–10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/PEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1b(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P050905WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/GB2009/001453	International filing date (day/month/year) 10/06/2009	(Earliest) Priority Date (day/month/year) 19/06/2008
Applicant CILAG GMBH INTERNATIONAL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

- b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).
- c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant
☒ the text has been established by this Authority to read as follows:

RE-USEABLE AUTO-INJECTOR WITH FILLING MEANS

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 4

☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention

- b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB2009/001453

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

An injection device having a first sub-assembly (110) comprises a housing (111) and a chamber (112). The chamber is disposed within the housing and has proximal and distal ends, an inner surface and an exit aperture (114). The sub-assembly comprises a stopper (113) movably disposed within the chamber. The stopper has an outer surface substantially in contact with the inner surface about its perimeter. The sub-assembly comprises a port (118) adapted to receive a container (1199) containing a fluid. The stopper is fixed with respect to the housing and movement of the port causes movement of the exit aperture in relation to the stopper.

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/001453

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/178 A61M5/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ✓	US 2003/036725 A1 (LAVI GILAD [IL]; YIGAL GJL [IL]; BAR-OR JONATHAN [IL]) 20 February 2003 (2003-02-20) paragraphs [0086], [0088] - [0089]; figures 16-30	1-2,5,11
X ✓	WO 00/06227 A1 (MEDI JECT CORP [US]) 10 February 2000 (2000-02-10)	1-2,7,11
Y	page 2, lines 8-24 page 5, line 1 - page 6, line 2; figures 1-3C	3-6,8-10
X ✓	US 6 162 199 A (GERINGER JOSEPH ROBERT [US]) 19 December 2000 (2000-12-19) figures 1-11	1,11

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
 "E" earlier document but published on or after the international filing date
 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
 "O" document referring to an oral disclosure, use, exhibition or other means
 "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
 "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
 "Z" document member of the same patent family

Date of the actual completion of the international search

29 September 2009

Date of mailing of the international search report

06/10/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040,
 Fax: (+31-70) 340-3016

Authorized officer

Björklund, Andreas

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/001453

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y ✓	US 2003/105430 A1 (LAVI GILAD [US]; YIGAL GIL [US]; TSALS IZRAIL [US]) 5 June 2003 (2003-06-05) paragraphs [0176] - [0183], [0188] - [0193]; figures 31-47 -----	1-11
Y ✓	US 2003/088216 A1 (PY DANIEL [US]) 8 May 2003 (2003-05-08) paragraph [0062]; figures 9-13 -----	1-11
A ✓	FR 2 654 938 A1 (GLAXO GROUP LTD [GB]) 31 May 1991 (1991-05-31) page 19, line 22 - page 20, line 17; figures 1-24 -----	1-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/001453

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003036725	A1	20-02-2003	NONE
WO 0006227	A1	10-02-2000	AU 5317699 A 21-02-2000 CN 1320050 A 31-10-2001 EP 1100566 A1 23-05-2001 JP 2002521147 T 16-07-2002
US 6162199	A	19-12-2000	NONE
US 2003105430	A1	05-06-2003	WO 03047663 A2 12-06-2003
US 2003088216	A1	08-05-2003	US 2007156102 A1 05-07-2007
FR 2654938	A1	31-05-1991	AR 246185 A1 29-07-1994 AT 400925 B 25-04-1996 AU 639955 B2 12-08-1993 AU 6691290 A 06-06-1991 BE 1003835 A5 23-06-1992 BR 9006006 A 24-09-1991 CA 2030742 A1 29-05-1991 CH 687234 A5 31-10-1996 CZ 9702029 A3 11-08-1999 DE 4037418 A1 29-05-1991 DK 281990 A 29-05-1991 ES 2038088 A6 01-07-1993 FI 905832 A 29-05-1991 GB 2239180 A 26-06-1991 GR 90100824 A 17-04-1992 HK 19295 A 17-02-1995 HU 61207 A2 28-12-1992 IE 904240 A1 05-06-1991 IL 96487 A 26-05-1995 IN 179332 A1 27-09-1997 IT 1243541 B 16-06-1994 JP 3222962 A 01-10-1991 JP 3399524 B2 21-04-2003 LU 87851 A1 25-08-1992 NL 9002598 A 17-06-1991 NO 905125 A 29-05-1991 NZ 236219 A 23-12-1992 PL 287996 A1 12-08-1991 PT 96005 A 31-08-1992 SE 469262 B 14-06-1993 SE 9003776 A 29-05-1991 RU 2108116 C1 10-04-1998 US 5137516 A 11-08-1992
FR 2654938	A1	ZA 9009514 A	27-11-1991

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2009/001453

International filing date (day/month/year)
10.06.2009

Priority date (day/month/year)
19.06.2008

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/178 A61M5/20

Applicant
CILAG GMBH INTERNATIONAL

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office

D-80298 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Björklund, Andreas

Telephone No. +49 89 2399-7310



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2009/001453

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2009/001453

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>3-4, 6, 8-10</u>
	No: Claims	<u>1-2, 5, 7, 11</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-11</u>
Industrial applicability (IA)	Yes: Claims	<u>1-11</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

- D1 US 2003/036725 A1 (LAVI GILAD [IL]; YIGAL GJL [IL]; BAR-OR JONATHAN [IL]) 20 February 2003 (2003-02-20)
- D2 WO 00/06227 A1 (MEDI JECT CORP [US]) 10 February 2000 (2000-02-10)
- D3 US 6 162 199 A (GERINGER JOSEPH ROBERT [US]) 19 December 2000 (2000-12-19)
- D4 US 2003/105430 A1 (LAVI GILAD [US]; YIGAL GIL [US]; TSALS IZRAIL [US]) 5 June 2003 (2003-06-05)
- D5 US 2003/088216 A1 (PY DANIEL [US]) 8 May 2003 (2003-05-08)
- D6 FR 2 654 938 A1 (GLAXO GROUP LTD [GB]) 31 May 1991 (1991-05-31)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-2; 5, 7 and 11 is not new in the sense of Article 33(2) PCT.

2.1. The document D1 discloses (the references in parentheses applying to this document):

An injection device (figs. 20-21) having a first sub-assembly comprising:

a housing (108);

a chamber (104) disposed within the housing and having proximal and distal ends, an inner surface and an exit aperture (front of chamber);

a stopper (134) movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and

a port (102) adapted to receive a container containing a fluid;

wherein the stopper is fixed with respect to the housing and movement of the port causes movement of the exit aperture in relation to the stopper (no relative movement of housing 104 and stopper 134 when they are moved in relation to the port 102).

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

2.2. Also the documents D2-D3 (see references in search report) disclose the subject-matter of claim 1 (Article 33(2) PCT).

2.3. A fillable auto-injector is disclosed in D4 (see references in search report). The subject-matter of claim 1 differs from this known auto-injector in that the stopper is fixed to the housing. However, it is presently not apparent which technical problem this difference solves. Furthermore, a stopper which is fixed with respect to the housing is known from D5 (see references in search report).

2.4. The subject-matter of claim 1 is not clear (Article 6 PCT) since the last lines of the claim defines a result to be achieved, i.e. "movement of the port causes movement of the exit aperture in relation to the stopper". However, in the present application it would have been appropriate to define the technical features necessary for achieving this result (PCT Guidelines 5.35).

2.5. Furthermore, the word "port" has no distinct meaning within the art of auto-injectors (Article 6 PCT).

2.6. Claim 1 contradicts the description and drawings (Article 6 PCT), since the claim defines that the stopper is fixed with respect to the housing, whereas page 8, line 30 - page 9, line 3 of the description and the drawings 7-8 imply that the stopper can move with respect to the housing.

2.7. The scope of claim 1 is much broader than what is actually justified by the disclosure of the application (Article 6 PCT and PCT guidelines 5.43). The application discloses only one embodiment of the injection device, namely an auto-injector, whereas the claims encompass any injection device. That the scope of the claims is much broader than what is justified is underlined by the description which describes that the problem to be solved is to overcome the complicated and expensive manufacturing process of auto-injectors with different medicaments.

2.8. The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 11, which therefore is also considered not new and not clear.

2.9. The application does not fulfil the requirements of Article 5 PCT. The application neither describes how the firing mechanism can expose the needle outside of the injection device nor how it can inject the fluid into the patient and then retract the needle (see PCT guidelines 5.45)

3. Dependent claims 2-10 as such do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, since they merely define trivial design options for injection devices which are known in the art, see documents D1-D6 and the corresponding passages cited in the search report.

4. Claim 1 is not drafted in the two-part form (Rule 6.3(b) PCT) and none of the claims are provided with reference signs (Rule 6.2(b) PCT).

5. Documents D1 and D4 are not mentioned in the description (Rule 5.1(a)(ii) PCT).

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPEA (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, QJ 11/2003, QJ 12/2003